REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested. Claims 1-3, 6-11 and 15 are pending in this application. Claim 1 is amended. Support for the amendment to claim 1 can be found throughout the specification as filed, in particular, page 3, line 22, of the PCT Application as filed. Claims 4-5 and 16-17 are cancelled. Claim 1 is the independent claim.

Furthermore, upon review of the enclosed Amendment and discovery of any additional references after further search and/or consideration, Applicants respectfully request that the Examiner contact Erin G. Hoffman, Reg. No. 57,752, to discuss the newly found references and/or possible claim amendments that may place the application in condition for allowance.

Interview Summary

Applicants appreciate Examiner Sassan and Examiner Sheikh's time during the interview conducted on Tuesday, May 25, 2010. Present at the interview were Applicant's U.S. representative Erin Hoffman, Mr. Hans Prins, the European Patent Attorney in the present application and Mr Mario Calomme, who works for the Assignee (Biominerals N.V.) and is knowledgeable in the field of the invention.

During the interview, Hans Prins summarized the major difference of the

present invention over the disclosure of Vanden Berghe stating that Vanden Berghe provides an extrudate of ortho silicic acid that is stabilized with a solvent agent. Vanden Berghe does not teach or suggest that choline stabilized ortho silicic acid can be used in extrudates. Also, it would not have been obvious to one skilled in the art that choline stabilized ortho silicic acid could be used in extrudates because the chemistry is completely different, and an extrudate of choline stabilized ortho silicic acid was not necessarily bioavailable.

The Examiner indicated further amendments to claim 1 would be helpful and tentatively agreed that amending the claims as shown in the preceding section of this amendment would overcome the current rejection. Applicants submit the claim amendments were prepared consistent with the Examiner's suggestions and thus, are believed to overcome the current rejections as detailed below.

Rejections under 35 U.S.C. § 103(a)

Vanden Berghe in view of Bronder

Claims 1-4, 6-11, and 15-16 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanden Berghe (EP 1 110 909 A1) in view of Bronder (US 5,922,360). Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 4 and 16 have been cancelled, and therefore, the rejection of claims 4 and 16 is now moot.

Referring to paragraphs 6, 7 and 9 of the Office Action, the argument of the Examiner may be summarized as a stabilized solution of orthosilicic acid with a stabilizing agent will remain stable, and can be processed further with any treatment that appears useful. Applicants respectfully disagree as is evidenced by Professor Vervaert's Declaration.

As stated in the Declaration, Applicants submit that it is not self-evident that a solution of orthosilicic acid with a stabilizing agent remains stable and bioavailable during further processing steps, which is particularly true for processing steps wherein the solution, and hence the stabilizing agent, is brought into contact with water.

The lack of evidence of maintenance of stabilization during further processing is particularly apparent for the use of a quaternary ammonium component, e.g., consisting essentially of choline as recited in amended claim 1, as the stabilizing agent. Orthosilicic acid has a tendency to polymerize, which is merely inhibited by the stabilizing agent. The stabilizing agent is hygroscopic, i.e., attracts water. Therefore, in the reasoning of a skilled person in the art, if water is added, the stabilizing agent will likely be encapsulated by water molecules. As such, the molecular interaction with the ortho silicic acid will be reduced, and the inhibition of polymerization will be removed.

In other words, use of a quaternary ammonium component as a

stabilizing agent would be expected to lead to stability problems during or as a consequence of further processing. As further illustration, the Example on page 2, line 16-18 of the present application states:

> *Direct filling of gelatine or methylcellulose capsules with a liquid matrix of choline stabilized silicic acid results in deformation and leaking of the capsule when incubated in stability tests.*

Referring to the Declaration, Professor Vervaert provides additional arguments why the use of choline or another quaternary ammonium component would have been non-obvious for a skilled person at the time of filing the application. First, there is a substantial difference between the solvent agents used by Vanden Berghe and the stabilizing agents of the present application (see paragraphs 18 and 19 of the Declaration). The difference resides in the chemical structure, the physico-chemical properties, and therefore, also in the type and form of stabilization.

The solvent agents of Vanden Berghe include compounds having 2 or more OH groups and have a boiling point above 130 °C. The stabilizing agent as recited in claim 1 is structurally different in that the stabilizing agent contains a nitrogen atom instead of OH groups, has a lower boiling point (e.g., the solution of choline and dry hydrogen chloride has a boiling point of 94.5 °C), and interacts differently with the ortho silicic acid (via complexation of the nitrogen atom in the stabilizing agent with a silanol group of orthosilicic acid).

As such, one skilled in the art would not have looked to a different type

of stabilizing agent from those disclosed in Vanden Berghe, e.g., stabilizing agent consisting essentially of choline as recited in amended claim 1, to give a similar result in terms of ability of extrusion and bioavailability.

Furthermore, as disclosed in Bronder, Vanden Berghe had knowledge of the choline stabilization as disclosed in Bronder and nevertheless did not propose the mixing of a choline-stabilized orthosilicic acid solution with a carrier such as cellulose, or the subsequent extrusion (see paragraph 19 of the Declaration). Effectively, Vanden Berghe teaches away from a stabilized agent as recited in claim 1 on page 2, lines 1-2 (paragraph 0009) stating that "this particulate carrier adsorbed ortho silicic acid has a bioavailability which is comparable or even improved over the stabilized formulation as disclosed in U.S. Patent No. 5,922,360.

Furthermore, extrusion/spheronisation technology is different from the field of mixing an orthosilicic acid solution (with cattle feed) and subsequent pressing into pellets or tablets (paragraph 21 of the Declaration). Additionally, the important requirement of bioavailability requires that no polymerization occurs, and therefore, one skilled in the art would not logically conclude that the use of choline as a stabilizing agent leads to useful results.

Also, Applicants respectfully submit that it could not be expected by a skilled person that the bioavailability of the silicic acid as recited in claim 1 is the same as the bioavailability of the solution of orthosilicic acid and choline (Bronder), and the bioavailability of the glycerol-stabilized orthosilicic acid

extruded pellets (Vanden Berghe).

The Applicants maintain, therefore, that the Action does not present the required "convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references," *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985), and that this rejection may not be properly maintained absent such reasoning.

The Applicants, therefore, respectfully request that the rejection to Claims 1-4, 6-11, and 15-16 under 35 U.S.C. § 103(a) be withdrawn.

Vanden Berghe in view of Bronder and Seguin

Claims 5 and 17 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanden Berghe in view of Bronder and further in view of U.S. Patent No. 6,335,457 to Seguin et al. (hereinafter "Seguin").

Claims 5 and 17 have been cancelled, and therefore, the rejection of claims 5 and 17 is now moot.

The Applicants, therefore, respectfully request that the rejection to Claims 5 and 17 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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